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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/557,105 | 11/14/2005 | Steven D. Kimmel | 17572-79(AP) | 5370 |

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| EXAMINER |
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WACHTEL, EMILY L

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| ART UNIT | PAPER NUMBER |
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4111

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11/15/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--------------------------------------|--------------------------------------|--|
| Office Action Summary | Application No. 10/557,105 | Applicant(s) KIMMEL ET AL. | |
| | Examiner Emily Wachtel | Art Unit 4111 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on October 11, 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) 2-4 and 6-12 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 is/are rejected.
- 7) ☒ Claim(s) 5 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>21 March 2006, 05 October 2007</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

Species I) Figs. 1-4

Species II) Figs. 5-9

Species III) Figs. 10-18

Species IV) Figs. 19-23

Species V) Figs. 24-32

Species VI) Figs. 33-36

Species VII) Figs. 37-40

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after

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the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

2. The claims are deemed to correspond to the species listed above in the following manner:

Species I: Claim 2

Species II: Claim 3

Species III: Claim 4

Species IV: Claims 1 and 5

Species V: Claims 1 and 6

Species VI: Claims 1 and 7-10

Species VII: Claims 11-12

The following claim(s) are generic: No claims are generic to all claims.

3. The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons:

The special technical features in claim 2 include a bolt, cocking stud, hammer, cup seal and rear spring. The special technical features in claim 3 are distinguished from claim 2 in that claim 3 includes a cylinder mounted for rotation with a plurality of chambers to allow for repeated injections and a firing pin. The special technical features in claim 4 include the tubular casing with hingable top and bottom half shells, a nose cap, a ratchet, and a cocking mechanism

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which engages the push rod and top half shell to compress the spring. Claim 1 is generic to claim 5 as claim 5 includes the limitations of claim 1 which are a housing, injection head, piston, energy source (spring in claim 5), and control mechanism (in claim 5 the control mechanism is the cylinder and sear). The special technical feature in claim 5 is the operational relationship between the cylinder rear end and sear which enables the spring to drive the piston without the need of an extra trigger and a cocking ring disposed in the housing bore. Claim 1 is generic to claim 6 as claim 6 includes the limitations of claim 1 which are a housing, injection head, piston, energy source (spring in claim 6), and control mechanism (trigger in claim 6). The special technical feature in claim 6 is the cocking grip disposed over the housing to compress the spring and is further distinguished from the features in claim 5 in that it includes the use of a trigger. Claim 1 is generic to claim 7 as claim 7 includes the limitations of claim 1 which are a housing, injection head, piston, energy source (gas manifold in claim 7), and control mechanism (valve controls gas manifold in claim 7). The special technical features in claim 7 is a gas manifold which introduces gas that is not in a cartridge disposed within the housing, further distinguishing it from claims 2 and 3 which also use gas. The special technical features of claim 11 include a plunger which is controlled by electrical current through a solenoid.

4. During a telephone conversation with Brent A. Johnson on October 23, 2007 a provisional election was made without traverse to prosecute the invention of Species IV claims 1 and 5. Affirmation of this election must be made by applicant in replying to this Office action. Claims 2-4, and 6-12 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

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Applicant submitted a suggested restriction requirement (SRR), however, the new rules did not go into effect on November 1, 2007. A different restriction requirement was made by the examiner as set forth above, and a species for prosecution was elected during the above telephone conversation. A first action on the merits is being made on the application as the new rules are not in effect.

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Specification

6. The disclosure is objected to because of the following informalities:

Page 4 line 20 --housing, cocking ring-- should be --housing and cocking ring--

Appropriate correction is required.

7. The use of the trademark BOTOX® has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Claim Objections

8. Claim 5 is objected to because of the following informalities:

Claim 5 recites:

a cylinder slidably disposed within said cocking ring and having a front end and a rear end with a chamber disposed proximate the front end;

an injection head disposed at the cylinder first end and in fluid communication with the chamber.

However, the cylinder first end is not recited with the description of the cylinder. The cylinder first end has been taken to be the same as the cylinder front end.

Appropriate correction is required.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Castellano (U.S. Patent 6,080,130).

With regards to claim 1 Castellano teaches **a needleless injector** (Fig. 1 reference number 10) **comprising: a housing** (Fig. 1 reference numbers 12 and 40); **an injection head disposed at one end of said housing** (Fig. 1 reference number 42); **a piston disposed in**

said housing for ejecting medicament through said injection head (Col. 2 line 55, Col. 3 lines 56-57, Fig. 1 reference number 50); **an energy source coupled to said piston for forcing said piston toward said injection head in order to effect the ejection of medicament** (Col. 3 lines 62-67 - gas chamber is providing energy, Fig. 1 reference numbers 18 and 14); **and a control mechanism for actuating said energy source** (Col. 2 lines 58-62 - control mechanism is a trigger, Fig. 1 reference number 22).

Allowable Subject Matter

11. Claim 5 is objected to as in paragraph 8 above but otherwise would be allowable. The following is a statement of reasons for the indication of allowable subject matter: the prior art of record does not teach the structural limitations set forth in claim 5 particularly a cocking ring extending from the housing distal end and having a rear portion slidably disposed on the housing bore and a cylinder slidably disposed within said cocking ring and having a front end and a rear end with a chamber disposed proximate the front end and a sear for releasably holding said piston in the second position with the spring compressed, said sear including a sear spring and a tapered end, the sear spring causing releasable engagement of said tapered end with the piston rear head; and said cylinder rear end disposed in an operational relationship with the sear tapered end for releasing said sear from the piston rear head enabling said spring to drive said piston to said first position. Taff et al. (U.S. Patent 4,447,225) teaches puller legs (Fig. 1 reference number 38) which cocks the piston (Col. 7 lines 36-38) and the medicament is injected upon the release of a latch activating a spring (Col. 8 lines 9-10). The puller legs do not have the same structure as the cocking ring or operational relationship required by claim 5. Umbaugh (U.S.

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Patent 6,083,197) teaches a needleless injector which has a cocking mechanism in the form of a cocking sleeve (Fig. 1 reference number 220) again; this mechanism does not have the same structure or operational relationship as the cocking ring in claim 5. Landau (US 2002/0151839) teaches a separate energizing unit which cocks the injector again; this mechanism does not have the same structure or operational relationship as the cocking ring in claim 5.

Conclusion

12. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Taff et al. (U.S. Patent 4,447,225), Umbaugh (U.S. Patent 6,083,197), Landau (US 2002/0151839), and Denne (US 2006/0287629) all disclose needleless injectors with cocking mechanisms and spring energy sources. Weston (US 2001/0039394) teaches a needleless injector which is actuated by contact with the skin.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Emily Wachtel whose telephone number is (571) 270-3648. The examiner can normally be reached on Monday through Thursday 7:30 AM to 5:00 PM (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sam Yao can be reached on (571) 272-1224. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Emily Wachtel/
Examiner, Art Unit 4111

/E. W./

/Sam Chuan C. Yao/

Supervisory Patent Examiner, Art Unit 4111